

Center for Regulatory Services, Inc.

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April 22, 2015

CBIC Control Number

364815

2015 APR 28 AM 11:50

RECEIVED
OPPT/CBIC

U.S. Environmental Protection Agency – East
Attn: TSCA Section 8(e)
Room 6428
1201 Constitution Avenue, NW
Washington, DC 20004

SUBJECT: TSCA 8(e) Notification
LVE L-99-147

The enclosed aquatic tox results that came the attention of JSR Micro, Inc., April 17, 2015, for the subject substance that is identified in Low Volume Exemption L-99-147.

The results of the aquatic tox testing of the substance is only identified as **ALFAX**.

96-hour LC50 Acute Toxicity Study in Fish (*Oryzias latipes*) - 10-100 mg/L
48-hour EC50 Acute Immobilization in *Daphnia magna* – 1.0-10 mg/L
72-hour EC50 Algal Growth Inhibition in *Pseudokirchneriella subcapitata* - <1.0 mg/L

Please feel free to contact the undersigned if you have any questions or if we can provide additional information.

Sincerely,



William A. Olson, Ph.D.
Agent
JSR Micro, Inc.

WAO:gbt
JSR-8E-ALFAX

Enclosures
3 Aquatic Tox Reports (6 pages)

cc: Y Ueda/T. Ozag, JSR (w/o Enclosures)

March 23, 2015

TEST REPORT

- A 96-hour Acute Toxicity Study in Fish -

Chemicals Evaluation and Research Institute,
Japan, Kurume
3-2-7, Miyanojin, Kurume-shi,
Fukuoka 839-0801, Japan

1. Test item ALFAX
2. Sponsor JSR Corporation
3. Objective To determine acute toxicity of the test item to Medaka
4. Dates

Exposure initiation	March 13, 2015
Exposure termination	March 17, 2015
5. Materials and methods

Test organism	Medaka (<i>Oryzias latipes</i>) (Total length: 2.2-2.6 cm Body weight: 0.093-0.18 g)
Exposure conditions	
Exposure duration:	96 hours
Test type:	Static regime
Test concentration:	100, 10, 1.0 mg/L as nominal concentration, and a control
Preparation of test solution:	The test item and dilution water were mixed to prepare each nominal concentration and stirred for 48 hours under shading. Then the suspension was filtered with a glass fiber filter (GB-140, 0.4 µm pore size, Toyo Roshi) by suction to prepare the test solution. The test item was treated under yellow fluorescent light.
Environmental conditions	
Dilution water:	Dechlorinated tap water
Temperature:	24±1°C
Number of organisms:	7 fish/test level
Volume of test solution:	Approximately 2.8 L/test level
Test vessel:	Glass tank
Lighting condition:	Shading condition (It was conducted under the yellow fluorescent light at the preparation of test item, handling of test organism, measurement of water quality and observation of test organisms, and under the room light at filtering the test solutions.)
Feeding:	No feeding
Aeration:	Conducted gently
Observation and measurements	
Observation of test organisms:	Mortality was observed under the yellow fluorescent light at 24, 48, 72 and 96 hours after exposure.
Size of organism:	Test organisms in the control were used for measuring total length and body weight after the end of exposure.
Water quality:	Dissolved oxygen concentration and pH were measured of 100 mg/L and the control at the start and end of exposure.
Appearance of test solution:	Colorless and clear (at the start of exposure: visual)

6. Result

96-hour median lethal concentration (96hr LC₅₀):

10-100 mg/L (nominal concentration)

Table Result of cumulative mortality and quality of test solution

Test level (mg/L)	Cumulative mortality (%)				Dissolved oxygen concentration (mg/L)		pH	
	24 hours	48 hours	72 hours	96 hours	At the start	At the end	At the start	At the end
Control	0	0	0	0	8.2	8.1	7.9	7.9
1.0	0	0	0	0				
10	0	0	0	0				
100	0	29	29	57	8.2	8.2	8.0	7.9

March 23, 2015

TEST REPORT

- A 48-hour Acute Immobilization Study in *Daphnia magna* -

Chemicals Evaluation and Research Institute,
Japan, Kurume
3-2-7, Miyanojin, Kurume-shi,
Fukuoka 839-0801, Japan

1. Test item ALFAX
2. Sponsor JSR Corporation
3. Objective To determine acute effects of the test item to daphnids
4. Dates

Exposure initiation	March 18, 2015
Exposure termination	March 20, 2015
5. Materials and methods

Test organism	<i>Daphnia magna</i> (Clone A)
Exposure conditions	
Exposure duration:	48 hours
Test type:	Static regime
Test concentration:	100, 10, 1.0 mg/L as nominal concentration, and a control
Preparation of test solution:	The test item and dilution water were mixed to prepare each nominal concentration and stirred for 48 hours under shading. Then the suspension was filtered with a glass fiber filter (GB-140, 0.4 µm pore size, Toyo Roshi) by suction to prepare the test solution. The test item was treated under yellow fluorescent light.
Environmental conditions	
Dilution water:	Dechlorinated tap water
Temperature:	20±1°C
Number of organisms:	20 daphnids/test level (5 daphnids/test vessel, 4 replicates)
Volume of test solution:	400 mL/test level (100 mL/test vessel, 4 replicates)
Test vessel:	100 mL glass beaker
Lighting condition:	Shading condition It was conducted under the yellow fluorescent light at the preparation of test solution, handling of test organism, measurement of water quality and observation of test organisms, and under the room light at filtering the test solutions.
Feeding:	No feeding
Aeration:	No aeration
Observation and measurements	
Observation of organisms:	Immobility was observed at 24 and 48 hours after exposure. Daphnids were considered immobile if they were not able to swim within 15 seconds after gentle agitation of the test vessel.
Water quality:	Dissolved oxygen concentration and pH were measured of 100 mg/L and the control at the start and end of exposure.
Appearance of test solution:	Colorless and clear (at the start of exposure: visual)

6. Result

48-hour median effective concentration (48hr EC₅₀):

1.0-10 mg/L (nominal concentration)

Table Result of immobility and quality of test solution

Test level (mg/L)	Immobility (%)		Dissolved oxygen concentration (mg/L)		pH	
	24 hours	48 hours	At the start	At the end	At the start	At the end
Control	0	0	8.8	8.8	7.6	7.6
1.0	0	5				
10	60	100				
100	100	100	8.9	8.8	7.6	7.7

March 30, 2015

TEST REPORT

— Algal Growth Inhibition Study in *Pseudokirchneriella subcapitata* —

Chemicals Evaluation and Research Institute,
Japan, Kurume
3-2-7, Miyanojin, Kurume-shi,
Fukuoka 839-0801, Japan

1. Test item ALFAX
2. Sponsor JSR Corporation
3. Objective To determine the effects of the test item on growth of algae
4. Dates

Exposure initiation	March 13, 2015
Exposure termination	March 16, 2015
5. Materials and methods

Test organism *Pseudokirchneriella subcapitata*

Exposure conditions

Exposure duration: 72 hours

Type test: Incubation with rotary shaking (approximately 100 rpm)

Test concentration: 100, 10, 1.0 mg/L as nominal concentration and a control

Preparation of test solution: The test item and medium were mixed to prepare each nominal concentration and stirred for 48 hours under shading. Then the suspension was filtered with a glass fiber filter (GB-140, 0.4 µm pore size, Toyo Roshi) by suction to prepare the test solution. The test item was treated under yellow fluorescent light.

Environmental conditions

Medium: OECD medium

Temperature: 21-24°C (not varied more than ± 2°C)

Initial cell concentration: 10⁴ cells/mL

Volume of test solution: 300 mL/test level (100 mL/ test vessel × 3 replicates)

Test vessel: Sterilized 300 mL Erlenmeyer flask with gas-permeable silicon rubber plug

Lighting condition: Nominal 90 µmol·m⁻²·s⁻¹
(within ± 20% of nominal, within ± 15% from the average light intensity)
Continuous illumination provided by fluorescent lights with wavelength range of 400-700 nm

Measurements

Biomass: Cell concentration was measured.

Condition of test solution: pH of 100 mg/L and control were measured at the start and end of exposure.

Appearance of test solution: Clear and colorless (at the start of exposure: visual)

6. Result

72-hour median effective concentration (72hr E_rC_{50}) [Based on growth rate (0-3d)]

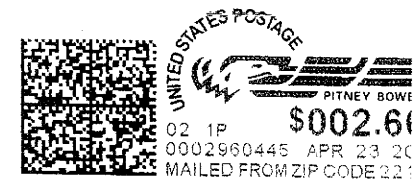
: <1.0 mg/L (nominal concentration)

No Observed Effect Concentration (NOEC) : <1.0 mg/L (nominal concentration)

Table Result of growth inhibition rate and quality of test solution

Test level (mg/L)	Growth inhibition rate (%) (Growth rate 0-3d)	pH	
		At the start	At the end
Control	-	7.8	8.0
1.0	55		
10	87		
100	120	7.8	7.9

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